K130524

Section 7: 510(k) Summary

MAY 2 2 2013

Introduction:

This document contains the 510(k) Summary for the modified BreathID® Hp System. The content of this summary is based on the requirements of 21 CFR 807.92(c).

Applicant / Manufacturer Name and Address:	Exalenz Bioscience Ltd. 4 Ha' Maayan St. Modiin, Israel 71700
510(k) Contact Person:	Clay Anselmo President Reglera LLC Email: anselmoc@reglera.com Phone: (303) 223-4303 Fax: (303) 832-6700
Date Prepared:	February 27, 2013
Device Name:	BreathID® Hp System
Classification:	Class I
Classification Name:	Campylobacter fetus serological agents
Regulation Number:	21 CFR 866.3110
Product Code:	MSQ

Predicate Devices:

The modified BreathID® Hp System is claimed to be substantially equivalent to the following legally marketed predicate device:

- BreathID® System, Exalenz Bioscience Ltd., K011668

General Description:

The modified BreathID® Hp System is a non-invasive breath test system for detecting the presence of *Helicobacter pylori* (*H. pylori*). The system consists of an electro-optical medical device with embedded software designed to measure and compute the changes in the ratio between $^{13}CO_2$ and $^{12}CO_2$ concentrations in the patient's exhalation and a test kit. The test kit consists of:

- IDcircuit™ - Oridion Nasal FilterLine™ (nasal cannula) (K980325)
- A 75mg ^{13}C-urea tablet
- A 4.3g package of powdered Citrica (citric acid)
- Drinking straw
- Package Insert (Instructions for Use)

The modified BreathID® Hp System measures and computes the ratio between $^{13}CO_2$ and $^{12}CO_2$ in the patient's exhalation before and after the ingestion of ^{13}C-urea. The change in the $^{13}CO_2$ / $^{12}CO_2$ ratio before and after ingestion of ^{13}C-urea is referred to as the Delta over Baseline (DOB).

The basis of the ^{13}C measurement method for both the modified and unmodified versions of the BreathID® System is a technology called Molecular Correlation Spectroscopy™ (MCS™). MCS™ is based on the concept of optical absorption of specific radiation emitted from CO_2 discharge lamps.

Intended Use / Indications for Use:

The Exalenz BreathID® Hp System is intended for use to continually and non-invasively measure changes in the $^{13}CO_2$ / $^{12}CO_2$ ratio of exhaled breath, which may be indicative of increased urease production associated with active *Helicobacter pylori* (*H. pylori*) infection in the stomach. The Exalenz BreathID® Hp System is indicated for use as an aid in the initial diagnosis and post treatment monitoring of *H. pylori* infection in adult patients. The Exalenz BreathID® Hp System consists of the IDkit:Hp™ and the BreathID® Hp test device.

The device is for use by trained health care professionals. To be administered under a physician's supervision.

Comparison of Technological Characteristics:

The key characteristics of the modified BreathID® Hp System are substantially equivalent to the prior cleared version of the device in all regards. Any differences are minor, are supported by testing, and do not raise new types of questions of substantial equivalence.

The modified BreathID® Hp System has the same fundamental scientific technology and principle of operation utilized in the unmodified BreathID® System. The technological modifications of the BreathID® Hp System are modifications to the configuration of the system and software revisions as a result of the modified hardware configuration.

This modified BreathID® Hp System is designed to be more compact, less expensive and easier to maintain than the unmodified system. In addition, the modified BreathID® Hp System either eliminates or consolidates components that have become redundant or obsolete.

Comparison of Intended Use:

There are no significant changes in the intended use or the indications for use between the modified BreathID® Hp System and the unmodified BreathID® System. The use environment, target user, and patient population of the modified BreathID® Hp System are the same as the unmodified device.

Substantial Equivalence:

The following tables summarize the similarities and differences of the Exalenz BreathID® System cleared in K011668 to the modified Exalenz BreathID® Hp System that is the subject of this 510(k) submission.

Table 7-1: Summary Table of Similarities Between the Unmodified BreathID® System and the Modified BreathID® Hp System

Specification / Characteristic	Exalenz Modified BreathID® Hp System	Exalenz BreathID® System (K011668)
Product Code	MSQ – Test, Urea (Breath or Blood	MSQ – Test, Urea (Breath or Blood
Regulation Number	21 CFR 866.3110 *Campylobacter fetus* serological reagents	21 CFR 866.3110 *Campylobacter fetus* serological reagents
Regulatory Class	Class I	Class I
Intended Use / Indications for Use	The Exalenz BreathID® Hp System is intended for use to continually and non-invasively measure changes in the $^{13}CO_2$ / $^{12}CO_2$ ratio of exhaled breath, which may be indicative of increased urease production associated with active *Helicobacter pylori* (*H. pylori*) infection in the stomach. The Exalenz BreathID® Hp System is indicated for use as an aid in the initial diagnosis and post treatment monitoring of *H. pylori* infection in adult patients. The Exalenz BreathID® Hp System consists of the IDkit:Hp™ and the BreathID® Hp test device. The device is for use by trained health care professionals. To be administered under a physician's supervision.	The Exalenz BreathID® System is intended for use to continually and non-invasively measure changes in the $^{13}CO_2$ / $^{12}CO_2$ ratio of exhaled breath, which may be indicative of increased urease production associated with active *Helicobacter pylori* (*H. pylori*) infection in the stomach. The Exalenz BreathID® System is indicated for use as an aid in the initial diagnosis and post treatment monitoring of *H. pylori* infection in adult patients. The Exalenz BreathID® System consists of the IDkit:Hp™, BreathID® test device and the system check accessory. The device is for use by trained health care professionals. To be administered under a physician's supervision.
Use Environment	By healthcare professionals in the clinical setting	By healthcare professionals in the clinical setting
Test Sample	Gas Sample continually transported to test measurement device by Exalenz (formerly Oridion) nasal cannula FilterLine™ (K980325)	Gas Sample continually transported to test measurement device by Exalenz (formerly Oridion) nasal cannula FilterLine™ (K980325)
^{13}C Urea	75mg tablet dissolved in water (NDA 21-314)	75mg tablet dissolved in water (NDA 21-314)
Applicable pre- and post- treatment	Yes	Yes

Specification / Characteristic	Exalenz Modified BreathID® Hp System	Exalenz BreathID® System (K011668)
Test Meal	4.3g Citrica (citric acid) dissolved in water	4.3g Citrica (citric acid) dissolved in water
Test Duration	10-30 minutes	10-30 minutes
Breath Collection	Continually over test duration	Continually over test duration
Cut-off Point	5.0 DOB per mil (post dose minus pre dose)	5.0 DOB per mil (post dose minus pre dose)
Organism	*Helicobacter pylori* in vivo	*Helicobacter pylori* in vivo
Reagent	^{13}C Urea	^{13}C Urea
Result	$^{13}CO_2/^{12}CO_2$ ratio – Molecular Correlation Spectroscopy™ (MCS™)	$^{13}CO_2/^{12}CO_2$ ratio – Molecular Correlation Spectroscopy™ (MCS™)

Table 7-2: Summary Table of Differences Between the Unmodified BreathID® System and the Modified BreathID® Hp System

Specification / Characteristic	Exalenz Modified BreathID® Hp System	Exalenz BreathID® System (K011668)
Operating System	Windows® CE	Windows® 95
Software Development Language / Environment	C# within Microsoft Visual Studio	LabView™ and its associated code generation functions
User Interface	Touchscreen monitor	Mechanical push button for operation
Footprint	Small footprint for desktop use with an integrated touchscreen monitor	Standalone device with wheels, including a monitor on an extendable arm
Data Acquisition Board	A custom data acquisition card	An off-the-shelf data acquisition card
Pneumatic Unit	1 pump	2 pumps
CO_2 sensor	$^{12}CO_2$ cell in $^{13}CO_2$ / $^{12}CO_2$ measurement subsystem	Capnograph
System Check (Quality Control)	Utilizes operator breath or pre-dose patient breath	Utilizes a supplied gas canister containing approximately 100% CO_2
In-Measurement Variability Reduction	Performed by the $^{13}CO_2$ / $^{12}CO_2$ measurement subsystem	Performed by the sealed reference cell, fibers, shutter and second detector

Discussion of Differences

All differences between the modified and unmodified versions of the device have been formally verified or validated to ensure that the changes do not impact device specifications or performance.

The device instructions for use have been updated to reflect the changes made to the operator / device interface and to incorporate the clinical performance characteristics of the device itself. The changes made do not alter the Indications / Contraindications or Warnings / Precautions.

The hardware / physical configuration has been modified in comparison to the unmodified BreathID® System. As demonstrated by the results of verification and validation, the modified hardware / physical configuration of the modified BreathID® Hp System does not have an effect on performance or substantial equivalence as compared to the unmodified BreathID® System.

Software changes have been implemented for the modified BreathID® Hp System related to the modified hardware configuration of the device. The software changes do not affect the safety and effectiveness of the modified BreathID® Hp System as compared to the unmodified BreathID® System.

Summary of Performance Bench Testing

Exalenz has performed verification and validation bench testing for demonstration of substantial equivalence of the modified BreathID® Hp System to the unmodified BreathID® System. The following key verification and validation bench tests are the most significant for establishing substantial equivalence:

- Gas Collection Verification
- System Check Verification
- Comparative Validation
- Analytical Studies
    - Precision Validation
    - Reproducibility Validation
- Software Verification and Validation

A summary of the Gas Collection Verification, System Check Verification, Software Verification and Validation, Comparative Validation, Precision Validation and Reproducibility Validation is provided below.

Gas Collection Verification

A Gas Collection Verification was performed to verify that the $^{12}CO_2$ cell of the $^{13}CO_2$ and $^{12}CO_2$ measurement subsystem of the BreathID® Hp System could adequately replace the Capnograph of the unmodified BreathID® System for measuring the CO_2 concentration in incoming gases. Twenty (20) tests were performed with breath samples that were not ^{13}C enriched from ten (10) different subjects. Each of the twenty (20) tests also included seven (7) DOB measurements from the measurement phase (MP) in various calibration ranges. The results of the Gas Collection Verification demonstrated that the DOB standard deviation of all measurement phase (MP) test results were within the specifications, all MP test sample concentrations were within the calibration range, and that all MP sample concentrations had a standard deviation of less than 0.2. Therefore, the $^{12}CO_2$ cell of the $^{13}CO_2$ and $^{12}CO_2$ measurement subsystem of the BreathID® Hp System has been verified to adequately replace the Capnograph of the unmodified BreathID® System for measuring the CO_2 concentration in incoming gases.

System Check Verification

A System Check Verification was performed to verify that operator breath or pre-dose patient breath could adequately replace the gas canister containing approximately 100% CO_2 for the purposes of the System Check, one of the Quality Control functions of the BreathID® Hp System and the unmodified BreathID® System. Twenty (20) tests were performed with breath samples from eleven (11) different subjects. Each of the twenty (20) tests also included seven (7) DOB measurements. The results of the System Check Verification demonstrated that in all cases where the ^{12}C curves

were randomly changed and a calibration was then required, the situation was correctly identified by the BreathID® Hp System and a calibration was performed. In all cases where the ^{12}C curves were unchanged and the calibration process was unable to expand the calibration range, the BreathID® Hp System correctly identified the situation and did not perform a calibration. In the case where the ^{12}C curve was unchanged, but the calibration range was expanded and a calibration was then required the BreathID® Hp System correctly identified the situation and performed a calibration. All test results following a System Check and calibration were within the specifications of the BreathID® Hp System. Additionally, all test results following a System Check that did not require calibration were within the specifications of the BreathID® Hp System. Therefore, the System Check Verification not only demonstrated that operator breath or pre-dose patient breath could be adequately used for the System Check procedure, but it also demonstrated that the calibration process was effective.

Software Verification and Validation

Software Verification evaluated all system functionality and consisted of evaluations of the software through unit, integration and system level testing, as well as code reviews. Software Validation consisted of various test cases to qualitatively test the software system of the BreathID® Hp System. The test case categories that were utilized for the software validation of the BreathID® Hp System were:

- H. Pylori Patient Mode Tests
- System Test
- Utilities, and
- System Failures

All test cases were implemented with a known input and an expected output. The expected output was visually compared against the actual output. All test cases were verified to have passing results.

Comparative Validation

A Comparative Validation was performed to evaluate the agreement of the modified BreathID® Hp System DOB measurements to its predicate device, the unmodified BreathID® System. The Comparative Validation was performed in accordance with the following standard:

- Clinical and Laboratory Standards Institute EP09-A2 *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline* – Second Edition

The Comparative Validation was performed with three *H. pylori* samples that included a high positive, low positive and moderate positive, as defined in the FDA Draft Guidance "Establishing Performance Characteristics of In Vitro Diagnostic Devices for the Detection of *Helicobacter pylori*," September 23, 2010. The Comparative Validation was performed with one modified BreathID® Hp System and one unmodified BreathID® System, executing two runs per day for five days. Each test run included three different combinations of baseline / post-ingestion gases and each combination of baseline / post-ingestion gases was consecutively tested twice. The modified BreathID® Hp System and the unmodified BreathID® System were evaluated simultaneously by connecting the two devices with a Y-Connector. Calibration was performed on the first day of the Comparative Validation. Table 7-3 below provides the results and analysis of the Comparative Validation.

Table 7-3: Distribution of DOB Measurements Between Modified and Unmodified BreathID® Systems

Expected DOB	Parameter	N	Mean	SD	Min	Median	Max
DOB: 4.5‰	DOB Modified BreathID®	20	4.96	0.350	4.3	4.97	5.6
	DOB Unmodified BreathID®	20	4.69	0.233	4.2	4.65	5.2
	Difference in DOB Between Devices		0.27	0.368	-0.5	0.28	1.0
DOB: 5.8‰	DOB Modified BreathID®	20	6.37	0.297	6.0	6.33	7.0
	DOB Unmodified BreathID®	20	6.07	0.266	5.5	6.07	6.5
	Difference in DOB Between Devices		0.30	0.366	-0.3	0.20	0.9
DOB: 13‰	DOB Modified BreathID®	20	14.09	0.424	13.2	14.03	14.9
	DOB Unmodified BreathID®	20	13.32	0.358	12.4	13.37	13.8
	Difference in DOB Between Devices		0.78	0.526	-0.3	0.75	1.7

A Pearson's correlation coefficient was calculated between the DOB measurements from the unmodified and modified BreathID® Systems. A correlation plot of the DOB measurements from the modified and unmodified BreathID® Systems is provided in Figure 7-1 below. The following values were calculated:

- $r = 0.9944$ (95% CI: [0.9904, 0.9966]
- $p < 0.0001$

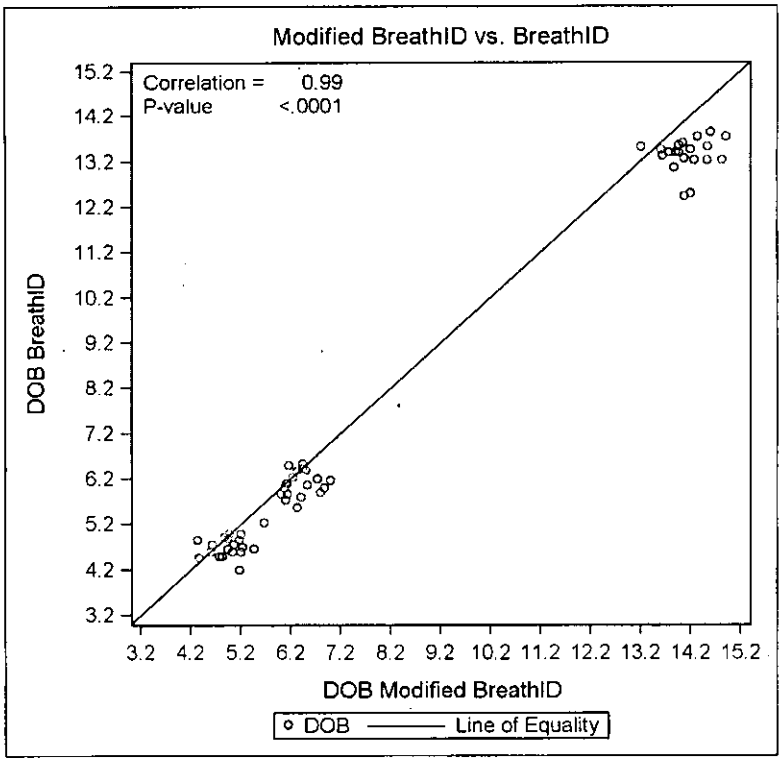

Figure 7-1: Correlation Plot of DOB Measurements from Unmodified and Modified BreathID® Systems

Table 7-4 below presents the slope and intercept of the Deming Regression, along with the respective 95% confidence interval (CI).

Table 7-4: Deming Regression Slope and Intercept

Deming Slope [95% CI]	Deming Intercept [95% CI]
1.06 [1.029, 1.095]	-0.05 [-0.302, 0.197]

Precision Validation

The Precision Validation was performed in accordance with the following standards:

- Clinical and Laboratory Standards Institute EP05-A2 *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline* – Second Edition, 2004
- Clinical and Laboratory Standards Institute EP15-A2 *User Verification of Performance for Precision and Trueness; Approved Guideline* – Second Edition, 2005

The Precision Validation was performed with three *H. pylori* samples that included a high positive, low positive and moderate positive, as defined in the FDA Draft Guidance "Establishing Performance Characteristics of In Vitro Diagnostic Devices for the Detection of *Helicobacter pylori*," September 23, 2010. The Precision Validation was performed using one modified BreathID® Hp System for twelve days, executing two runs per day. Each test run included three different combinations of baseline / post-ingestion combinations, and each combination of baseline / post-ingestion gases was consecutively tested twice. Calibration was performed on the first and seventh days of the Precision Validation. The tabulated accuracy results and the tabulated repeatability results are provided in Tables 7-5 and 7-6 below, respectively.

Table 7-5: Precision Validation DOB Accuracy Results

Expected DOB	Accuracy (Mean)	95% CI
DOB: 4.3‰	4.67	[4.5 – 4.85]
DOB: 5.9‰	5.85	[5.52 – 6.17]
DOB: 15.5‰	15.78	[15.57 – 15.99]

Table 7-6: DOB Repeatability and Between-Day Precision

Expected DOB	Parameter	SD Value	95% CI	CV
DOB: 4.3‰	Repeatability	0.559	[0.499 – 0.635]	12.0%
	Between-Days Precision	0.603	[0.525 – 0.681]	12.9%
DOB: 5.9‰	Repeatability	0.479	[0.427 – 0.544]	8.2%
	Between-Days Precision	0.691	[0.621 – 0.760]	11.8%
DOB: 15.5‰	Repeatability	0.689	[0.615 – 0.784]	4.4%
	Between Days Precision	0.738	[0.664 – 0.811]	4.7%

Reproducibility Validation

The Reproducibility Validation was performed in accordance with the following standards:

- Clinical and Laboratory Standards Institute EP05-A2 *Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline* – Second Edition, 2004
- Clinical and Laboratory Standards Institute EP15-A2 *User Verification of Performance for Precision and Trueness; Approved Guideline* – Second Edition, 2005

The Reproducibility Validation was performed with three *H. pylori* samples that included a high positive, low positive and moderate positive, as defined in the FDA Draft Guidance "Establishing Performance Characteristics of In Vitro Diagnostic Devices for the Detection of *Helicobacter pylori*," September 23, 2010. The Reproducibility Validation was performed using three devices in three different sites for five days. Two test runs were executed per day by different operators. Each test run utilized three different combinations of baseline / post-ingestion gases and each combination of baseline / post-ingestion gases was consecutively tested three times. Calibration was performed on the first day of the Reproducibility Validation. The tabulated accuracy results and the tabulated reproducibility results are provided in Tables 7-7 and 7-8 below, respectively.

Table 7-7: Reproducibility Validation DOB Accuracy Results

Expected DOB	Accuracy (Mean)	95% CI
DOB: 4.5‰	4.82	4.60 – 5.05
DOB: 5.9‰	6.18	4.97 – 7.40
DOB: 15.5‰	15.69	15.41 – 15.98

Table 7-8: DOB Reproducibility, Between-Day Reproducibility and Between-Operator Reproducibility

Expected DOB	Parameter	SD Value	95% CI	CV
DOB: 4.5‰	Reproducibility	0.524	0.483 – 0.573	10.9%
	Between-Days Reproducibility	0.533	0.455 – 0.624	11.0%
	Between-Operators Reproducibility	0.524	0.444 – 0.619	10.9%
DOB: 5.9‰	Reproducibility	0.563	0.518 – 0.615	9.2%
	Between-Days Reproducibility	0.648	0.576 – 0.712	10.6%
	Between-Operators Reproducibility	0.697	0.612 – 0.780	11.4%
DOB: 15.5‰	Reproducibility	0.536	0.494 – 0.586	3.4%
	Between-Days Reproducibility	0.536	0.479 – 0.585	3.4%
	Between-Operators Reproducibility	0.538	0.485 – 0.591	3.4%

Summary of Clinical Validation

Exalenz conducted a clinical validation to demonstrate that the modified BreathID® Hp System is substantially equivalent to the unmodified BreathID® System.

A single center, non-randomized, blinded, comparative study was conducted to compare the modified BreathID® Hp System to the unmodified BreathID® System. The breath test was performed according to the standard procedure described in the device's instructions for use and routine clinical practice while the subject was connected simultaneously to both the BreathID® Hp System and the unmodified BreathID® device via two standard nasal cannulae. The outcome measures of both devices were used for the comparison.

In order to prevent a spectrum bias, the breath test was performed in addition to, and independent of the local clinical practice. In cases were a serum blood test was performed, these blood tests were the only means used to diagnose the presence of *H. pylori*. In other cases, where the investigator did not feel a blood test was warranted (change in diet prescribed, or symptoms not specific to *H. pylori*), the patient was periodically followed up at the clinic as routine general practice with no eradication therapy prescribed. In these cases, only if symptoms persisted or became more related to *H. pylori* infection, was the patient sent for blood tests. The breath testing was performed by a site technician and not in the proximity of the Principal Investigator. The breath test results were made available to the treating physician (Principal Investigator) only once the patient's management protocol had been determined. Thus, the test results from both devices were masked from the treating physician and did not have an impact on the patient's treatment.

The clinical study was conducted in compliance with its protocol and in accordance with the ethical principles under Investigational Review Board (IRB) approval consistent with Good Clinical Practice (GCP) and with applicable regulatory requirements. Table 7-9 below presents the subjects' accountability and the subjects' baseline characteristics per protocol (PP).

Table 7-9: Subject Baseline Characteristics

Parameter		Statistic	PP
Age		N	79
		Mean (SD)	49.2 (16.54)
		Median [min-max]	50.5 [18.4 – 87.8]
Height		N	77
		Mean (SD)	164.0 (9.90)
		Median [min-max]	163.0 [142.0 – 185.0]
Weight		N	79
		Mean (SD)	69.5 (16.65)
		Median [min-max]	66.0 [43.0 – 117.0]
BMI		N	77
		Mean (SD)	25.7 (4.92)
		Median [min-max]	24.4 [17.4 – 44.4]
Sex	Male	% (n/N)	41.77% (33/79)
	Female	% (n/N)	58.23% (46/79)
Ethnicity	African-American	% (n/N)	1.27% (1/79)
	Asian-Pacific	% (n/N)	68.35% (54/79)
	Caucasian	% (n/N)	12.66% (10/79)
	Hispanic	% (n/N)	15.19% (12/79)
	Other	% (n/N)	2.53% (2/79)

PP Analysis Set

The PP analysis set consisted of all subjects enrolled in the study that did not have any major protocol deviations and had no other relevant *H. pylori* testing prior to enrollment in the study, which was defined as no positive test results within 2012 and no negative test results within three months prior to enrollment. The cross tabulation of the diagnosis as assessed by both the modified and unmodified BreathID® Systems in the PP analysis set is provided in Table 7-10 below. The PP analysis set included 79 valid subjects per the protocol.

Table 7-10: PP Analysis Set Agreement

		Unmodified BreathID® System		Total
		Positive	**Negative**	
BreathID® Hp System	**Positive**	17	2	19
	Negative	---	60	60
Total		17	62	79

- Positive percent agreement = 100% * 17/17 = 100% [95% CI (81.6, 100)]
- Negative percent agreement = 100% * 60/62 = 97% [95% CI (89.0, 99.1)]

These results satisfied the acceptance criterion of ≥ 95% and therefore the study was successful in demonstrating equivalence of the two devices.

Conclusion

The modified Exalenz BreathID® Hp System is substantially equivalent with respect to the indications for use, intended use, use environment, target users, patient population, technological characteristics, and performance characteristics to the following legally marketed predicate device, K011668 – BreathID® System, Exalenz Bioscience Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2013

Exalenz Bioscience Ltd.
c/o Clay Anselmo
President
11925 W I-70 Frontage Rd, North Suite 900
Wheat Ridge, CO 80033

Re: K130524
Trade/Device Name: BreathID Hp System
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: I
Product Code: MSQ
Dated: February 27, 2013
Received: February 28, 2013

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, Ph.D., M.Sc.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K130524

Device Name: BreathID® Hp System

Indications for Use:

The Exalenz BreathID® Hp System is intended for use to continually and non-invasively measure changes in the $^{13}CO_2$ / $^{12}CO_2$ ratio of exhaled breath, which may be indicative of increased urease production associated with active *Helicobacter pylori* (*H. pylori*) infection in the stomach. The Exalenz BreathID® Hp System is indicated for use as an aid in the initial diagnosis and post treatment monitoring of *H. pylori* infection in adult patients. The Exalenz BreathID® Hp System consists of the IDkit:Hp™ and the BreathID® Hp test device.

The device is for use by trained health care professionals. To be administered under a physician's supervision.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Raquel A. Peat -S
2013.05.16 16:54:24 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K130524